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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,588	04/26/2001	Stephanie M. Cortese	FZIO6605US1 SRM/DBB	8737

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EXAMINER
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O'SULLIVAN, PETER G

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/843,588

Applicant(s)

CORTESE ET AL.

Examiner

Peter G. O'Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 8,16,17,55-58 and 77-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-15,18-54 and 59-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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Claims 1-80 are pending in this application which should be reviewed for errors.

In response to the requirement for the election of a single disclosed species, applicants elected a composition having carboxymethylcellulose, polyethylene oxide,  $\text{Ca}^{++}$ , and thrombin. Claims 8, 16, 17, 55-58 and 77-80 are withdrawn as not embracing the elected species.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6, 7, 9-15, 18-29, 32-45, 48-50, 53, 54 and 59-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polyacids of the scope of claim 2, does not reasonably provide enablement for all polyacids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants' generic claims claim a composition comprising a polyacid which would encompass, for example, alkanetricarboxylic acids as well as proteins comprising aspartic acid or glutamic acid residues. Applicants' invention is a hemostatic composition which forms a gel, membrane or foam. Applicants' examples are drawn to polyethylene oxide and CMC compositions. The art shows certain types of polyacids used in conjunction with polyoxyalkylenes and polyalkylene glycols to have the required physical properties. Applicants' claims would require undue experimentation to make and/or use compositions comprising polyacids

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outside of the scope of those of the scope of claim 2, but falling within the scope of claim 1, such as those comprising alkanetrioic acids as well as proteins.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 21 recite the limitation of a gel. There is insufficient antecedent basis for this limitation in the claim.

Claims 26 and 44 are objected to as substantial duplicates.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9-15, 18-54, 59-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al., U.S. 6,034,140, taken with Jacob et al., U.S. 5,985,312, and Okada et al., U.S. 6,113,943. Schwartz et al. disclose bioresorbable

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compositions of carboxypolysaccharides and polyether complexes and which possess anti-adhesion, bioadhesive, bioresorptive and antithrombogenic properties wherein the carboxypolysaccharides and polyethers used as well as pH, and amounts of components used overlap applicants'. Additionally Schwartz et al. disclose overlapping processes of making their compositions. The compositions of Schwartz et al. may comprise further drugs including antithrombogenic agents (s. Col. 10 and 11, bridging paragraph). The compositions of Schwartz et al. differ from those of applicants in not having thrombin or  $\text{Ca}^{++}$ . Jacob et al. discloses metal compounds such as those of calcium can be used to increase the bioadhesiveness of polymers such as carboxylic acid containing polymers and polyoxyalkylenes (s. Col. 5, top, Col. 6, bottom, and Col. 7) in drug delivery compositions. Okada et al. disclose thrombin to be a hemolytic drug suitable for use in a polycarboxylic acid sustained release compositions (s. Col. 12, ll. 19-23). It would have been prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teaching of the cited references to make applicants' compositions and to expect to obtain a hemostatic composition with additional properties of bioadhesiveness, bioresorptive properties, etc.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9-15, 18-26, 44-54, 59, 60 and 63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,869,938 taken with Schwartz et al., U.S. 6,034,140, in view of Okada et al., U.S. 6,113,943. Patent '938 claims compositions of polyacids and polyethers useful in reducing adhesions and optionally containing further drugs overlapping applicants' with the exception that thrombin is not claimed as a component. Schwartz et al., disclose similar compositions to have anti-adhesion, bioadhesive, bioresorptive and antithrombogenic properties. Okada et al. disclose thrombin to be a hemolytic drug suitable for use in a polycarboxylic acid sustained release compositions (s. Col. 12, ll. 19-23). It would have been prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teaching of the cited references to make applicants' compositions and to expect to obtain a hemostatic composition with additional properties of anti-adhesiveness, bioadhesiveness, bioresorptive properties, etc.

Claims 1-7, 9-15, 18-54, 59-76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No.'s 6,017,301 and 6,034,140 in view of Jacob et al., U.S. 5,985,312 and

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Okada et al., U.S. 6,113,943. Patent No's '301 and '140 claim compositions of polyacids and polyethers useful in reducing adhesions having bioadhesiveness and/or other other properties and optionally containing further drugs overlapping applicants' with the exception that  $\text{Ca}^{++}$  and thrombin are not claimed as a components. Jacob et al. disclose metal compounds such as those of calcium can be used to increase the bioadhesiveness of polymers such as carboxylic acid containing polymers and polyoxyalkylenes (s. Col. 5, top, Col. 6, bottom, and Col. 7) in drug delivery compositions. Okada et al. disclose thrombin to be a hemolytic drug suitable for use in a polycarboxylic acid sustained release compositions (s. Col. 12, ll. 19-23). It would have been prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teaching of the cited references to make applicants' compositions and to expect to obtain a hemostatic composition with additional properties of anti-adhesiveness, bioadhesiveness, bioresorptive properties, etc.

Claims 1-7, 9-15, 18-26, 44-54, 59, 60, and 63-76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,133,325 in view of Jacob et al., U.S. 5,985,312 and Okada et al., U.S. 6,113,943. Patent No. '325 discloses compositions of polyacids and polyethers useful in reducing adhesions having bioadhesiveness and/or other other properties and optionally containing further drugs overlapping applicants' with the exception that  $\text{Ca}^{++}$  and thrombin are not claimed as a components. Jacob et al. disclose metal compounds such as those of calcium can be used to increase the bioadhesiveness of polymers such as carboxylic acid containing polymers and polyoxyalkylenes (s. Col. 5,

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top, Col. 6, bottom, and Col. 7) in drug delivery compositions. Okada et al. disclose thrombin to be a hemolytic drug suitable for use in a polycarboxylic acid sustained release compositions (s. Col. 12, ll. 19-23). It would have been prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teaching of the cited references to make applicants' compositions and to expect to obtain a hemostatic composition with additional properties of anti-adhesiveness, bioadhesiveness, bioresorptive properties, etc.

Claims 1-7, 9-15, 18-25, 44-54, 59, 60, and 63-76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,566,345 in view of Schwartz et al., U.S. 6,034,140, Jacob et al., U.S. 5,985,312 and Okada et al., U.S. 6,113,943. Patent No's '345 discloses compositions of polyacids and polyethers useful in reducing adhesions and optionally containing further drugs overlapping applicants' with the exception that  $\text{Ca}^{++}$  and thrombin are not claimed as a components. Schwartz et al., disclose similar compositions to have anti-adhesion, bioadhesive, bioresorptive and antithrombogenic properties. Jacob et al. disclose metal compounds such as those of calcium can be used to increase the bioadhesiveness of polymers such as carboxylic acid containing polymers and polyoxyalkylenes (s. Col. 5, top, Col. 6, bottom, and Col. 7) in drug delivery compositions. Okada et al. disclose thrombin to be a hemolytic drug suitable for use in a polycarboxylic acid sustained release compositions (s. Col. 12, ll. 19-23). It would have been prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teaching of the cited references to make



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applicants' compositions and to expect to obtain a hemostatic composition with additional properties of anti-adhesiveness, bioadhesiveness, bioresorptive properties, etc.

Claims 1-7, 9-15, 18-25, 44-54, 59, 60, and 63-76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,906,997 in view of Jacob et al., U.S. 5,985,312 and Okada et al., U.S. 6,113,943. Patent No. '997 discloses compositions of polyacids and polyethers useful in reducing adhesions having bioadhesiveness and/or other other properties and optionally containing further drugs overlapping applicants' with the exception that  $\text{Ca}^{++}$  and thrombin are not claimed as a components. Jacob et al. disclose metal compounds such as those of calcium can be used to increase the bioadhesiveness of polymers such as carboxylic acid containing polymers and polyoxyalkylenes (s. Col. 5, top, Col. 6, bottom, and Col. 7) in drug delivery compositions. Okada et al. disclose thrombin to be a hemolytic drug suitable for use in a polycarboxylic acid sustained release compositions (s. Col. 12, ll. 19-23). It would have been prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teaching of the cited references to make applicants' compositions and to expect to obtain a hemostatic composition with additional properties of anti-adhesiveness, bioadhesiveness, bioresorptive properties, etc.

No claim is allowed.

Any inquiry concerning this communication should be directed to Peter G. O'Sullivan at telephone number (571)272-0642.



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